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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,916	06/27/2003	Yoshiaki Nishiya	223380	8116

23460 7590 07/16/2010  
LEYDIG VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601-6731

EXAMINER
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DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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07/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/607,916		NISHIYA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Pensee T. Do		1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6,8 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,6, 8, 15-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.                                                         | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

### ***Priority***

This application, 10607916, PG Pub. No. 20040126902 , filed 06/27/2003 claims foreign priority to 188140/2002 , filed 06/27/2002, and also claims foreign priority to 230533/2002 , filed 08/07/2002 and claims foreign priority to 267170/2002 , filed 09/12/2002. The effective filing date is 6/27/2002.

### ***Amendment Entry & Claims Status***

The amendment filed on April 20, 2010 has been acknowledged and entered.

Claims 1, 6, 8, 15-24 are pending.

Claims 1, 6, 8 are being examined.

Claims 15-24 are withdrawn from further consideration due to a non-elected invention.

### ***Withdrawn Rejection(s)***

Rejection under 102 in the previous office action is withdrawn herein.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Weindel et al. (WO 01/37291 submitted by Applicants).

Weindel teaches a magnetic carrier for a biological substance which is a ferromagnetic iron oxide (see page 5, lines 5-9) core/particle coated with a glass shell (see page 11, lines 27-30) comprising a composite oxide of silicon and aluminum (see page 11, lines 16-18). The iron oxide particle has an average diameter of 5 and 500 nm which is equivalent to 0.005-0.5 microns ( $\mu\text{m}$ ) and covers the claimed range of 0.1-0.5  $\mu\text{m}$ . (see page 5, lines 13-16). Regarding the concentration of the coating composite (3%-100% Wt of the particle), Weindel teaches that glass materials contains 70.67 Mol. % of  $\text{SiO}_2$ ; 14.33 Mol. % of  $\text{B}_2\text{O}_3$  and 5 Mol.% of  $\text{Al}_2\text{O}_3$ . (see page 10, lines 8-10). Regarding the aspect ratio, the saturation magnetization and the coercive force of the particle, since Weindel teaches the same magnetic carrier with the same structural composition, the magnetic carrier must possess the same properties as claimed in the present invention with respect to the aspect ratio, the saturation magnetization and the coercive force. Regarding the limitation of the particle can bind a nucleic acid, since the particle of Weindel has the same characteristics as that of the present invention, it would be able to bind a nucleic acid. In fact, Weindel teaches the magnetic glass particle can bind to nucleic acid molecule. (page 7, lines 29-32).

Regarding claims 6 and 8, Weindel teaches that the ferromagnetic iron oxide particle is a magnetite (see page 5, lines 10-13).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan et al. (US 6,548,264) in view of Kleiber et al. (US 6,255,477).

Tan teaches a magnetic carrier which is a ferromagnetic iron oxide particle coated with a silica coating. (see col. 4, lines 12-15; col. 4, lines 61-62). The particle has an average size of 1 nm to 1000 nm which covers the claimed range of 100 nm to 500 nm (0.1  $\mu$ m - 0.5  $\mu$ m). (see col. 4, lines 26-35). Regarding the concentration of silica (3-100 wt% of the particle), Tan teaches that 100  $\mu$ l NH<sub>4</sub>OH equals to 28-30 wt% (see col. 12, line 62) and using 50  $\mu$ l of TEOS (silica) (see col. 13, lines 3-5). Thus, since 100  $\mu$ l is equivalent to 28-30 wt%, 50  $\mu$ l of TEOS (silica) must be half of 28-30 wt% which is 14-15 wt% and such range falls within the range of 3-100 wt% as claimed in the present invention. Regarding the aspect ratio, the saturation magnetization and the coercive force of the particle, since Tan teaches the same magnetic carrier with the same structural composition, the magnetic carrier must possess the same properties as claimed in the present invention with respect to the aspect ratio, the saturation magnetization and the coercive force. Regarding the limitation of the particle can bind a nucleic acid, since the particle of Tan has the same characteristics as that of the present invention, it would be able to bind a nucleic acid. In fact, Tan teaches the silica

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coating comprises functional groups that can bind to nucleic acid molecule. (see col. 6, lines 36-42).

However, Tan fails to teach a coating comprising a composite oxide of silicon and aluminum.

Kleiber teaches a magnetic core coated with a layer of glass shell. The glass shell comprises a sodium boroaluminium silicate glass which has proven to be especially effective in isolating biological materials such as nucleic acids. (see col. 2, lines 10-21; col. 3, lines 17-50).

Since Tan teaches that the silica coating can comprises a mixture of silica and aluminum oxides (see col. 5, lines 53-60) and Kleiber teaches that glass coating such as a composite of silicon oxide, aluminum oxide and boron oxide is effective in isolating biological materials such as nucleic acids, it would have been obvious to one of ordinary skill in the art to combine the teachings of Kleiber and Tan. One of ordinary skill in the art would have been motivated to use the sodium boroaluminum silicate glass coating on the magnetic particles of Tan because such coating is effective in isolating nucleic acids and such coating can create magnetic particles with surprising characteristics when used to isolate biological materials, especially nucleic acids. (see Kleiber col.3, lines 33-36). Other advantages are that if the ferromagnetic particles coated with such glass coating when have not been brought in contact with a magnetic field sediment out, they can be resuspended easily and quickly by shaking the solution. The ferromagnetic particles can be easily collected at a specific location in the sample fluid by means of a

magnet. The fluid is then separated from the particles, and, therefore, from immobilized biological materials, i.e. nucleic acids. (see Kleiber, col. 4, lines 43-58).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 6, 8 have been considered but are moot in view of the new ground(s) of rejection.

Applicants amended the claims to recite the particle is coated with a composite oxide of silicon and aluminum and argue that Tan fails to teach such limitation. Applicants also submit that the teaching in Tan that the shell can be "an inorganic oxide such alumina or silica or mixtures thereof" (col. 5, lines 53-60) is not equivalent to "a composite oxide of silicon and aluminum" as required by the amended pending claims. In particular, a composite oxide of silicon and alumina can be represented by a  $\text{SiO}_2$ - $\text{Al}_2\text{O}_3$  composition, in which the silica and alumina share at least one bond.

This is found persuasive and therefore the 102 rejection by Tan is withdrawn.

However, the new grounds of rejection teach such limitation. In particular, Weindel teaches the shell comprises a composite of silicon and aluminum wherein the silicon and aluminum share at least one bond. (see Weindel, page 22, p. 10).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/  
Examiner, Art Unit 1641

/Jacob Cheu/

Primary Examiner, Art Unit 1641